

# HUMAN SPINAL DISC PROSTHESIS WITH HINGES

This is a continuation-in-part of U.S. patent application Ser. No. 08/681,230, filed Jul. 22, 1996, now U.S. Pat. No. 5,674,296 and which is a continuation-in-part of U.S. patent application Ser. No. 08/339,490, filed Nov. 14, 1994, which is abandoned.

## BACKGROUND OF THE INVENTION

This invention relates generally to human prostheses, and especially to spinal column vertebral disc prostheses. The invention also relates to surgical procedures for preparing the patient to receive a vertebral disc endoprosthesis, and for implanting that endoprosthesis in the patient's spine.

The herniation of a spinal disc and the often resultant symptoms of intractable pain, weakness, sensory loss, incontinence and progressive arthritis are among the most common of debilitating processes affecting mankind. If a patient's condition does not improve after conservative treatment, and if clear physical evidence of nerve root or spinal cord compression is apparent, and if correlating radiographic studies (i.e., MRI or CT imaging or myelography) confirm the condition, surgical removal of the herniated disc may be indicated. The process of discectomy—as the name implies—involves the simple removal of the disc without attempt to replace or repair the malfunctioning unit. In the United States in 1985, over 250,000 such operations were performed in the lumbar spine and in the cervical spine.

Statistics suggest that present surgical techniques are likely to result in short-term relief, but will not prevent the progressive deterioration of the patient's condition in the long run. Through better pre-operative procedures and diagnostic studies, long-term patient results have improved somewhat. But it has become clear that unless the removed disc is replaced or the spine is otherwise properly supported, further degeneration of the patient's condition will almost certainly occur.

In the mid-1950's and 60's, Cloward and Smith & Robinson popularized anterior surgical approaches to the cervical spine for the treatment of cervical degenerative disc disease and related disorders of the vertebrae, spinal cord and nerve root; these surgeries involved disc removal followed by interbody fusion with a bone graft. It was noted by Robinson (Robinson, R. A.: The Results of Anterior Interbody Fusion of the Cervical Spine, J. Bone Joint Surg., 440A: 1569-1586, 1962) that after surgical fusion, osteophyte (bone spur) reabsorption at the fused segment might take place. However, it has become increasingly apparent that unfused vertebral segments at the levels above and below the fused segment degenerate at accelerated rates as a direct result of this fusion. This has led some surgeons to perform discectomy alone, without fusion, by a posterior approach in the neck of some patients. However, as has occurred in surgeries involving the lower back where discectomy without fusion is more common as the initial treatment for disc herniation syndromes, progressive degeneration at the level of disc excision is the rule rather than the exception. Premature degenerative disc disease at the level above and below the excised disc can and does occur.

Spine surgery occasionally involves fusion of the spine segments. In addition to the problems created by disc herniation, traumatic, malignant, infectious and degenerative syndromes of the spine can be treated by fusion. Other procedures can include bone grafts and heavy duty metallic

rods, hooks, plates and screws being appended to the patient's anatomy; often they are rigidly and internally fixed. None provide for a patient's return to near-normal functioning. Though these procedures may solve a short-term problem, they can cause other, longer term, problems.

A number of attempts have been made to solve some of the problems described above by providing a patient with spinal disc prostheses, or artificial discs of one sort or another. For example, Steffee, U.S. Pat. No. 5,031,437, describes a spinal disc prosthesis having upper and lower rigid flat plates and a flat elastomeric core sandwiched between the plates. Frey et al., U.S. Pat. Nos. 4,917,704 and 4,955,908, disclose intervertebral prostheses, but the prostheses are described as solid bodies.

U.S. Pat. Nos. 4,911,718 and 5,171,281 disclose resilient disc spacers, but no inter-connective or containing planes or like elements are suggested, and sealing the entire unit is not taught.

It is the primary aim of the present invention to provide a vertebral disc endoprosthesis which will perform effectively and efficiently within a patient's spine over a long period of time, and which will not encourage degeneration of or cause damage to adjacent natural disc parts.

It is a related objective to provide a new vertebral disc endoprosthesis surgical procedure which will decrease post-operative recovery time and inhibit post-operative disc, vertebral body and spinal joint degeneration.

It is yet another object to provide a method of installing the endoprosthesis so as to accurately mate the endoprosthesis with an adjacent specifically formed bone surface. An associated object is to provide an endoprosthesis which will encourage bone attachment to, and growth upon, adjacent outer surfaces of the endoprosthesis.

Yet another object is to provide a vertebral endoprosthesis in which the parts are non-oncogenic.

Still another object is to provide a vertebral disc endoprosthesis having a resilient element to accommodate shocks and other forces applied to the spine.

Another object is to provide a highly effective vertebral endoprosthesis which includes several disc endoprostheses and one or more prosthetic vertebral bodies. A related object is to provide these elements in a pre-assembled array for implantation in a patient.

## SUMMARY OF THE INVENTION

To accomplish these objects, the invention comprises a resilient body formed of a material varying in stiffness from a relatively stiff exterior portion to a relatively supple central portion. A concave-convex means at least partly surrounds that resilient body so as to retain the resilient body between adjacent vertebral bodies of a patient's spine. If medical considerations so indicate, several disc endoprostheses can be combined with one or more endoprosthetic vertebral bodies in an entire assembly.

To implant this endoprosthesis assembly, information is obtained regarding the size, shape, and nature of a patient's damaged natural spinal discs. If one or more of the patient's vertebral bodies also require replacement, information about those bodies is also obtained. Thereafter, one or more prosthetic disc units and interposed prosthetic vertebral body units are constructed and preassembled in conformity with that information. Finally, the completed and conformed prosthetic disc and vertebral body assembly is implanted in the patient's spine.

Other objects and advantages of the invention will become apparent upon reading the following detailed

description and upon reference to the drawings. Throughout the drawings, like reference numerals refer to like parts.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a fragmentary vertical view of a portion of a human spine in which is installed a novel vertebral disc endoprosthesis embodying the present invention;

FIG. 2 is a fragmentary side elevational view similar to FIG. 1 showing the elements of a patient's spine and having a novel vertebral disc endoprosthesis embodying the present invention installed therein;

FIG. 3 is a sectional view taken substantially in the plane of line 3—3 in FIG. 1;

FIG. 4 is an exploded view of the novel vertebral disc endoprosthesis;

FIG. 5 is a vertical fragmentary view of a patient's spine similar to FIG. 1, but showing a series of novel disc endoprosthesis units installed in the spine and interconnected to one another;

FIG. 6 is a fragmentary sectional view of a patient's spine similar to FIG. 3 and taken along line 6—6 in FIG. 5, but showing a natural upper vertebral body, and upper endoprosthetic disc; an adjacent endoprosthetic vertebral body; a second or lower endoprosthetic disc; and a second or lower natural vertebral body;

FIG. 7 is a sectional view taken substantially in the plane of line 7—7 of FIG. 6;

FIG. 8 is a fragmentary side elevational view of the assembly shown in FIG. 6; and

FIG. 9 is a fragment vertical view, similar to FIG. 1, of a portion of a human spine in which is installed a variant form of the novel vertebral disc endoprosthesis the variant form having a prosthetic longitudinal ligament;

FIG. 10 is a sectional view taken substantially in the plane of line 10—10 in FIG. 9;

FIG. 11 is a top view of a retainer means for use with a vertebral disc endoprosthesis;

FIG. 12 is a sectional view taken substantially in the plane of line 12—12 of FIG. 11;

FIG. 13 is a side view of a vertebral disc endoprosthesis having a groove for receiving the retainer means; and

FIG. 14 is a cross-sectional view of the retainer means in use.

### DETAILED DESCRIPTION

While the invention will be described in connection with a preferred embodiment and procedure, it will be understood that it is not intended to limit the invention to this embodiment or procedure. On the contrary, it is intended to cover all alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

Turning more specifically to FIGS. 1-3, a portion of a human spine 10 is shown. The illustrated spine 10 has been subjected to a discectomy surgical process. To discourage degeneration of or damage to the natural vertebral bodies 12 and 14 and their respective facet joints, in accordance with the invention, a vertebral disc endoprosthesis 18 is affixed between the adjacent natural vertebral bodies 12 and 14. Here this vertebral disc endoprosthesis 18 comprises a resilient disc body 20 having a relatively stiff annular gasket exterior portion 22 and a relatively supple nuclear central portion 24. The annular gasket 22 can be formed from a suitable biocompatible elastomer in the range of approxi-

mately 70-90 durometer hardness and the nuclear central portion 24 can be formed from a softer biocompatible elastomeric polymer of approximately 30 durometer hardness. In an alternate embodiment, the gasket 22 can extend over and under the nuclear central portion 24 so as to fully enclose it within a thin layer. In a further embodiment, the nuclear central portion, the gasket, and the thin layer extension are molded together to form one piece having different durometer hardnesses.

Concaval-convex means 30 surround the resilient body 20 to retain the resilient body 20 between the adjacent natural vertebral bodies 12, 14 in a patient's spine 10. To this end, as shown in FIG. 3, the concaval-convex means 30 comprise two generally L-shaped supports 32 and 34. The supports 32, 34 each have confronting first concaval-convex legs 42, 44, each leg being of relatively constant cross-sectional thickness. Each leg 42, 44 has an outer convex surface 52, 54 for engaging the adjacent bone of the natural vertebral bodies 12, 14. Corresponding inner concave surfaces 62, 64 in confronting array retain the resilient body 20 in its illustrated compressive force shock-absorbing position. These supports 32 and 34 can undergo principle movement away from one another, but only limited secondary translational, rotational and distractive motion will occur. Each support 32, 34 has a second wing or leg 72, 74 extending generally perpendicularly to the first legs 42, 44 respectively, and adapted for affixation to the adjacent bone structure. To carry out aspects of the invention described below, this affixation is effectively accomplished by cannulated screw devices 82, 84 which may be of a biodegradable type manufactured by Zimmer of Largo, Fla. Each device 82, 84 comprises a screw 92, 94; and a screw anchor 102, 104 adapted to threadably receive the screw extends radially into and seats within the bone structure 12, 14 as especially shown in FIG. 3. The screws 92, 94 may terminate in the anchor or alternately proceed through an open ended anchor and terminate in the bone of the vertebral body 12, 14 directly. The anchors 102, 104 may be close-ended, open ended, or of the expansion type.

To discourage and prohibit migration of fluids between the endoprosthesis 18 and adjacent parts of the anatomy, a seal member 110 is attached to the supports 32, 34 so as to surround the resilient body 20 which is comprised of the gasket 22 and nucleus 24, in accordance with another aspect of the invention. Here, this seal member 110 comprises a flexible sheet material having a multiplicity of pores. Preferably, the pores are from about 5 microns to about 60 microns in size. A flexible, strong polymer sheet material from which this seal is formed can be a Kevlar-like material, or it can be Goretex-like material, expanded PTFE, or other appropriate biocompatible material, such as polyether, polyurethane, or polycarbonate urethane membranes, can be used. Kevlar material is offered by the E. I. DuPont de Nemours Company of Wilmington, Del. and Goretex material is offered by the W. T. Gore Company of Flagstaff and Phoenix, Ariz. The seal material may be lined on its interior surface, its exterior surface, or both surfaces with silicone or any suitable sealing material so as to render the flexible sheet material substantially impervious to the passage of any fluid. A watertight seal is perfected when the seal 110 is glued or otherwise affixed to the legs 42, 44 and mediate portions of the legs 72, 74 as suggested in FIGS. 1-3.

In the space beneath the seal member 110 and between the disc body 20 and the concave surfaces of legs 42, 44, a lubricant may be used. The lubricant used may be saline or an appropriate liquid or particulate material lubricant.

In an alternative embodiment, the watertight seal between the endoprosthesis 18 and adjacent parts of the anatomy can

be provided by developing a groove 402 completely encircling the periphery of each of the legs 42, 44. In this embodiment, the legs 72, 74 may be attached to the circumferential groove member 402 by laser-welding or other suitable means. If the legs 72, 74 are of polymeric material, they may be attached by mechanical or adhesive techniques. Only one of the grooves is shown in FIG. 13. In this embodiment, the seal member 410 is provided with a beaded edge 412 for each groove. Additionally, a retaining band 415 is provided for each groove to retain the seal member 410 in groove 402. The retaining bands 415 can be in the form of a biocompatible monofilament wire of, for example, stainless steel or titanium, a synthetic polymer cable or a braided wire cable. As shown in FIG. 11, each retaining band is crimped anteriorly by a crimping sleeve 420. Of course, more than one crimping sleeve may be used, if necessary. Alternately, the retaining band is fastened by laser-welding. Although one sealing arrangement consisting of the groove, beaded edge and retaining band is shown in FIG. 14, it should be understood that the sealing arrangement on the concaval-convex leg of the other support is identical in design and function.

In use, the seal member 410 is placed about the concaval-convex means 30. The retaining bands 415 are then placed adjacent to the respective groove 402 and crimped anteriorly, thereby fitting the bands into the grooves. Each beaded edge 412 prevents the slipping of the seal member underneath the retaining band. Thus, the retaining band, the groove and the beaded edge all cooperate to provide a water-tight seal to prevent the migration of fluids between the endoprosthesis 18 and adjacent parts of the anatomy. Glue can also be used to affix the seal member to the concaval-convex means 30 as a supplemental means for perfecting the seal.

In a first embodiment, the first legs 42, 44 are formed as an integral piece with the respective second wings or legs 72, 74. In the alternate embodiment of FIG. 3, however, the first legs 42, 44 are hingedly attached to the respective second legs 72, 74. A hinge 43, 73 is provided at the point from which the second leg 72, 74 extends generally perpendicularly to the first leg 42, 44. The hinge is not intended to function as such after being installed, but only during installation so as to allow better alignment of the endoprosthesis with the biologically variable anterior surface of the respective vertebral body. Once the endoprosthesis is installed and affixed via the screw devices, the hinge will no longer move.

These hinges 43, 73 may take any of the several known forms. Each hinge can be a rod and socket hinge, a pin type hinge, or a slip joint fitting, or it can be a web or a membrane type hinge of metal or plastic.

The second wings or legs 72, 74 may be made of a suitable metal such as titanium or a polymeric material. Alternately, each leg 72, 74 including its associated hinge element, can be made of a biodegradable polymeric material. When the legs 72, 74 are made of biodegradable material, the screws 92, 94 used for affixing the legs to the adjacent bone structure may be of the standard shoulder screw type in order to maintain firm fixation to the screw anchors 102, 104 after biodegradation of the legs 72, 74.

Legs 72, 74 can be of a thin construction that allows some degree of flexibility so as to promote a better mating of the legs to the anterior aspect of the vertebral body 12, 14.

The legs can have a central closed oblong slot to accommodate a screw or other fixation device. Should a second endoprosthesis device be placed at an adjoining level, the leg

72, 74 would be placed on top of the corresponding leg from the adjacent device. The screw 92, 94 or other fixation device would then pass through the closed oblong slot of the overlapping legs 72, 74.

In accordance with another aspect of the invention, the supports 32, 34 are formed of a biocompatible metal which may contain chromium cobalt or titanium. Surface roughening or titanium beading 112, 114 on the exterior surfaces 52, 54 of legs 42, 44 encourages positive bonding between the adjacent bone and the convex surfaces 52, 54. Over time, bone fuses or grows into the surface roughening, thereby adhering to the legs 42, 44 in a rigid and strong manner.

As suggested in FIGS. 9 and 10, a prosthetic longitudinal ligament 250 can be connected between the screws 92, 94 to limit motions between elements of the spine 10 in the area where the endoprosthesis 18 is implanted. This strap 250 may be made of the Kevlar-like material or the Goretex-like material described above, or it may be made of any other strong biocompatible material. The ligament 250 may also be considered a spacer or cover for providing some degree of separation between overlying soft tissues in the body and the anterior-most surfaces of the device. However, it is not designed for restricting or preventing motion in the disc body. A biodegradable washer can be provided around the screws 92, 94 at a point between the strap 250 and the respective wing or leg 72, 74. When biodegradable washers are used, the screws 92, 94 used for affixing the legs to the adjacent bone structure may be of the standard shoulder screw type in order to maintain firm fixation to the screw anchors 102, 104 after biodegradation of the washers.

When a ligament is used in the embodiment of the device having hinged legs 92, 94, the prosthetic longitudinal ligament structure can comprise several parallel bands of material separated by approximately 10 mm.

In accordance with another aspect of the invention, multiple endoprosthetic disc units can be placed in series with a straddling interlock appendage providing stability and fixation as shown in FIG. 5. Entire portions of a patient's spine can be replaced by a series of interconnected endoprosthetic vertebral bodies and endoprosthetic disc units. FIGS. 6-8 show an upper natural vertebral body unit 312 to which an upper endoprosthetic body 308 has been attached. A lower natural vertebral body 314 has attached, at its upper end, an endoprosthetic disc unit 318. Between these endoprosthetic disc units 308 and 318 is an endoprosthetic vertebral body 320. As suggested by FIG. 7, the endoprosthetic vertebral body 320 need not be irregularly shaped in cross sectional aspect; rather, manufacturing processes may suggest that it have a circular cross-sectional shape. As shown in FIGS. 6 and 8, this endoprosthetic vertebral body 320 comprises a titanium element 321, to which are attached the preformed upper and lower endoprosthetic vertebral body upper and lower concaval-convex elements 322, 324. Each concaval-convex element 322, 324 is attached to the prosthetic vertebral body 320, as shown in FIG. 7, by extending set screws 330 through the titanium vertebral body 321 into a stem-like projection 331 extending from each of the concaval-convex elements 322, 324. A hole 360 in the body 320 accommodates the stem-like projections 331 of the concaval-convex elements 322 and 324. The stem-like projection 331 of the concaval-convex elements 322 and 324 is used only in conjunction with a prosthetic vertebral body implant construction 320.

An ear 340 is affixed, as by weldments 341, to a leg 342 extending from a concaval-convex element 322 as illustrated in FIGS. 6 and 8. An anchor 352 can be threaded into the